UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MEDEVA PHARMA SUISSE A.G., and PROCTER & GAMBLE PHARMACEUTICALS, INC.,

Plaintiffs,

v.

ROXANE LABORATORIES, INC.

Defendant.

Civil Action No. 07-5165 (FLW)(TJB)

DEFENDANT'S REPLY BRIEF IN SUPPORT OF APPEAL FROM THE MAGISTRATE JUDGE'S NOVEMBER 30, 2009 LETTER ORDER

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INTRODUCTION

Plaintiffs' opposition to Roxane's appeal ignores the issue: whether the Court has the authority to require a generic drug applicant to provide advance notice of its decision to market its FDA-approved drug. Such a notice requirement is in effect a 45-day TRO entered without any examination of the "four factors" and without the requirement of a bond. No authority permits a court to grant such relief. Plaintiffs' complaints about long-since-resolved discovery issues are irrelevant to the legal issue, and are false in any event.

I. NO AUTHORITY SUPPORTS THE MAGISTRATE JUDGE'S IMPOSITION OF A 45-DAY NOTICE PERIOD

First, plaintiffs' contention that Roxane bears a "heavy burden" on this appeal is not true. The issue here is a question of law: whether the Court has the authority to impose a 45-day waiting period on a generic applicant's launch of an FDA-approved product. This issue is not one of discretion, but instead of legal authority, and must be reviewed *de novo*. *See* 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A); *Haines v. Liggett Group, Inc.*, 975 F.2d 81, 91 (3rd Cir. 1992); *Cooper Hosp./Univ. Med. Ctr. V. Sullivan*, 183 F.R.D. 119, 127 (D.N.J. 1998).

Plaintiffs' argument boils down to an assertion that it would be convenient for them and for the Court if Roxane were required to provide notice in anticipation of any launch of its proposed product. Merely because an arrangement is convenient, however, does not mean that any statutory authority exists to impose it on an unwilling party. Here, a statute, 21 U.S.C. § 355(j)(5)(B)(iii), provides restrictions on when a generic applicant may launch an approved product. Such a launch may be made at the end of the 30-month period unless the court extends that period. A court can extend that period only if "either party to the action failed to reasonably cooperate in expediting the action." Even plaintiffs admit that the Magistrate Judge did not

extend the 30-month period, and they do not ask for and make no attempt to support such an extension. Other than the statute, the only authority a Court has to prevent such a launch is its equitable jurisdiction; it can enter a TRO or a preliminary injunction. Both those forms of relief, however, are circumscribed by Fed. R. Civ. P. 65, and by principles of equity.

The only authority plaintiffs cite, *Eli Lilly & Co. v. Sicor Pharmaceuticals*, No. 06 CV 238, 2008 WL 2518622 (S.D. Ind. June 20, 2008), provides no support for their argument. There, the parties agreed to the imposition of a notice period to provide for the resolution of a possible preliminary injunction. The court merely extended that agreed-to period from 60 to 90 days, to effect the purpose of the agreement. Neither the parties nor the court discussed whether a court could impose such a requirement over a party's objection.

Plaintiffs' other authorities deal with issues surrounding the court's management of a litigation itself. The distinction between all those cases and this one is the same: in none of them did the court impose any prohibition or restriction on any activity of any party except activities in the litigation itself. That is, in none of those cases did the court restrict any commercial or business activities of a party. No party was required to forgo or delay any business activity. The 45-day notice here, on the other hand, has the potential to deprive Roxane of significant economic gain. For example, if Roxane were to obtain approval after the expiration of the statutory 30-month period and decide to launch its product immediately, it would have to wait another six weeks to do so, thereby losing a substantial profit opportunity. Plaintiffs' would not have to secure that 45-day waiting period as they would against an improvidently granted injunction, and Roxane would have no recourse should the Court determine that Roxane should not be enjoined.

II. ROXANE IS WILLING TO ACCEPT THE NOTICE PERIOD IN EXCHANGE FOR A LIKE NOTICE PERIOD FOR A CITIZEN'S PETITION

Although the Court did not have authority to issue the 45-day order, Roxane expressed a willingness to accept it in exchange for an agreement or order that plaintiffs provide 45 days notice of any citizen's petition directed to Roxane's product. A non-meritorious citizen's petition is a well known tactic to stall the approval of generic drug products. If Roxane is required to provide notice of an impending launch, then plaintiffs can time the filing of their citizen's petition so that it arrives at the FDA just in time to prevent that launch. Although plaintiffs bridle at the suggestion that citizen's petitions and their timing are tactical devices, nowhere in their papers do they represent that they will not use the procedure in that way.

Plaintiffs' argument that their "first amendment rights" are somehow curtailed by a requirement that they provide notice before filing a citizen's petition is fatuous. The right to petition the government does not imply that anyone can at anytime demand to see any government official or file and have considered any paper. The citizen's petition process already is subject to extensive regulation, but plaintiffs do not assert that those regulations are infringements of their constitutional liberties. Likewise, a requirement that plaintiffs provide the same notice that defendants provide is not a significant, or indeed any, restriction on plaintiffs' petition rights.

III. PLAINTIFFS' IRRELEVANT OBSTRUCTION ARGUMENT IS FALSE

Although the issue is irrelevant to the question whether the Court can order Roxane not to market an FDA-approved product absent proof that plaintiffs are entitled to injunctive relief, Roxane was not at all dilatory or obstructive in conducting and providing discovery. In fact, Roxane completed its production of documents to plaintiffs' counsel by January, 2009. Plaintiffs, on the other hand, continued to resist document discovery for months after that, until

ordered to do so in June, 2009. (Jones Dec., Exhibit A.) In fact, months after Roxane had completed its production, plaintiffs produced a deluge of paper—more than 100,000 pages. Also, plaintiffs engaged in the legal gamesmanship of attempting to disqualify Roxane's expert, an effort that tied up discovery until the Court rejected plaintiffs' contentions in October, 2009. Plaintiffs also attempted to impose ridiculous conditions on the depositions of the inventors—third parties whom plaintiffs' counsel represented. Those depositions were delayed until the Magistrate Judge could strike down plaintiffs' efforts. (Jones Dec., Exhibit B.) Roxane served on plaintiffs a Rule 30(b)(6) notice on March 19, 2009. (Jones Dec., Exhibit C.) Plaintiffs did not produce its witnesses in response to that notice until November, 2009. Plaintiffs' recurring tactic was to refuse to provide discovery to Roxane, and then demand that Roxane agree to a hurried-up schedule. Naturally, Roxane opposed such efforts, and agreed to a trial schedule only when plaintiffs finally agreed to comply with their own discovery obligations. The statute requires both sides to act expeditiously in the litigations. 21 U.S.C. § 355(j)(5)(B)(iii). If plaintiffs are upset about the trial schedule, they need only look to their own conduct for the reason.

Plaintiffs also claim that Roxane manufactured a batch of tablets and did not tell plaintiffs about them until December 2009. Plaintiffs have deliberately omitted the relevant facts: this batch was commissioned by counsel for Roxane specifically for the use by one of Roxane's experts in connection with a study he carried out at counsel's request. The batch of tablets and its creation is classic "work product." Roxane disclosed the batch when it disclosed the expert's report, which describe the experiments conducted with it. Plaintiffs likewise disclosed their experts' activities for the first time when they submitted their own expert reports. That is the way the Federal Rules work: a party is under no obligation to disclose its experts' work on a day-

to-day basis while it is being conducted. Until the time for exchanging expert reports, that work is work product and not discoverable. In fact, that arrangement is set forth in a stipulation plaintiffs' counsel drafted and the parties executed in July, 2008. (Jones Dec., Exhibit D.) Plaintiffs' failure to explain the circumstances surrounding this batch of tablets is inexcusable.

Plaintiffs' allegations of obstruction are irrelevant to the issue raised by this appeal: whether the Court has the authority to impose a 45-day injunction on Roxane's lawful marketing activities. Those allegations are false in any event.

CONCLUSION

For the foregoing reasons and for the reasons expressed in Roxane's opening brief, the Magistrate Judge's order should be reversed.

Respectfully submitted,

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